

KAEMPFER CROWELL
Robert McCoy, No. 9121
1980 Festival Plaza Drive
Suite 650
Las Vegas, Nevada 89135
Telephone: (702) 792-7000
Facsimile: (702) 796-7181
Email: rmccoy@kcnvlaw.com

Attorneys for Defendants St. Jude Medical, S.C.
and Advanced Neuromodulation Systems, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

SHARON HARDMAN, individually,

Plaintiff,

vs.

ST. JUDE MEDICAL, S.C., INC., a foreign
corporation; ADVANCED
NEUROMODULATION SYSTEMS, INC., a
foreign corporation; DOES I through X; and
ROE CORPORATIONS I through X,

Defendants.

Case No. 2:14-cv-02131-RFB-VCF

**STIPULATED CONFIDENTIALITY
AGREEMENT AND PROTECTIVE
ORDER**

Plaintiff Sharon Hardman and defendants St. Jude Medical, S.C. and Advanced
Neuromodulation Systems, Inc. (collectively, the “Parties”) stipulate to the following
Confidentiality Agreement and Protective Order pursuant to Federal Rule of Civil Procedure
26(c).

I. SCOPE OF ORDER

Disclosure and discovery in this case may involve production of confidential,
proprietary, and private information for which special protection from public disclosure and from
any purpose other than prosecuting this litigation would be warranted. This Order applies
equally to **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material (each of which is
defined below) produced/provided and designated as such in this case.

1 **II. DISCOVERY PHASE**

- 2 A. **Materials Subject to Protection:** Material produced or disclosed that is subject
3 to designation as “**CONFIDENTIAL**” or “**HIGHLY CONFIDENTIAL**”
4 pursuant to this Order includes any document, including, without limitation, any
5 writings, video or audio tapes, electronically stored information in any form, oral
6 or written testimony, answers to interrogatories, responses to requests for
7 admission, deposition testimony, deposition transcripts and exhibits, trial
8 testimony, trial transcripts and exhibits, and other responses to requests for
9 information or any tangible thing produced by a Party or non-party in this matter,
10 as well as pleadings, motions, affidavits, letters and briefs that quote, summarize
11 or contain **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material.
- 12 B. **Definition of Confidential Material:** A producing party may designate as
13 “**CONFIDENTIAL**” any material the producing party believes in good faith
14 constitutes or discloses information that qualifies for protection, and specifically
15 information that is trade secret or other confidential research, development, or
16 commercial information, and materials that are deemed confidential under Federal
17 Drug Administration (“FDA”) statutory and regulatory law and Health Insurance
18 Portability and Accountability Act (“HIPAA”) statutory and regulatory law.
- 19 C. **Definition of Highly Confidential Material:** Confidential information may be
20 further designated as “**HIGHLY CONFIDENTIAL**” if a Defendant produces
21 materials that it believes in good faith would, if disclosed, cause substantial
22 economic harm to its competitive position because it is highly confidential
23 research and development material on a new product that has not been approved
24 or cleared by the FDA or a similar regulatory body or reflects its price
competitiveness in the market or marketing business strategies concerning a
current or new product. Counsel will inform the producing party of its intent to
disclose such information to any individual who is currently, or who at any time
during the pendency of this action becomes, an employee or consultant to a

competitor of the producing party in the neurostimulation business, or is an employee or consultant to an entity actively investigating entering such business, and thereafter will follow the procedures for disclosure of such materials to such individual as provided in Paragraph II.K of this Order.

D. **Permitted Redactions:** Confidential documents that are produced pursuant to a valid document request, deposition notice, or subpoena may include redactions for information covered by the attorney client privilege, work product doctrine and/or any other applicable privilege, information regarding other products unrelated to the product at issue in this action, and information that is wholly irrelevant to this matter and not reasonably calculated to lead to the discovery of admissible evidence. The parties also recognize that certain FDA, other governmental agency, and federal statutes and regulations such as HIPAA require redaction of certain information prior to production by Defendants and that Defendants will comply with those requirements and redact such information as directed.

E. **Production by Non-Parties:** Non-parties may invoke the terms of this Protective Order by marking any documents containing confidential information that they produce or disclose in accordance with Paragraphs II.B and II.C. A Party may designate material produced or disclosed by non-parties that contain that Party's "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" as such.

F. **Access to Confidential Material:** Access to any **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material shall be limited to:

- (1) the Court and its staff;
- (2) attorneys of record, their law firms (including paralegals and clerical staff), and their outside vendors, including messenger, copy, coding, document collection, document processing, and other clerical-services vendors not employed by a party or its attorneys;
- (3) persons shown on the face of the **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material to have authored or received the material;

- 1 (4) court reporters retained to transcribe testimony;
- 2 (5) the parties, including employees and officers of Defendants, their
- 3 subsidiaries, and affiliates;
- 4 (6) any person whose deposition is taken by any party, so long as such
- 5 disclosure is made during the course of the deposition and the deponent
- 6 (other than a present or former employee, consultant, expert, or other
- 7 person under the control of Defendants, their subsidiaries, and
- 8 affiliates) signs an Agreement To Be Bound in the form of Exhibit A;
- 9 (7) outside independent persons (*i.e.*, persons not currently employed by or
- 10 otherwise associated with any party) who are retained by a party to
- 11 provide assistance as mock jurors or focus group members or the like,
- 12 and/or to give testimony in this action, so long as such persons sign an
- 13 Agreement To Be Bound in the form of Exhibit A;
- 14 (8) experts or consultants retained to assist attorneys, provided that:
- 15 (a) the expert or consultant has read this Protective Order in advance
- 16 of disclosure, has agreed in writing to be bound by it, and has
- 17 executed an Agreement To Be Bound in the form of Exhibit A to
- 18 that effect, a copy of which counsel for the party who retained the
- 19 expert or consultant will keep and produce at the disclosing party's
- 20 request. Nothing in this provision shall require any party to
- 21 disclose the identity of any expert prior to those dates set forth by
- 22 the Court regarding production of expert disclosures; and
- 23 (b) if the expert or consultant is a current employee, consultant, or
- 24 agent of any competitor of Defendants or any of their affiliates or
- subsidiaries, Plaintiff must first notify counsel of record for
- Defendants in writing. Such notice shall provide a reasonable
- description of the outside independent person to whom disclosure
- is sought sufficient to permit objection to be made. If Defendants

or their subsidiaries and affiliates object in writing to such disclosure within 14 days after receipt of notice, no disclosure shall be made until the party seeking disclosure obtains the prior approval of the Court or Defendants or their subsidiaries and affiliates; and

(9) a jury empanelled in this matter.

Unless in open Court or ordered by the Court, persons not entitled to **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material under this paragraph shall not be present when **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material is offered as an exhibit, quoted, or referenced in a deposition, hearing, trial, or other proceeding.

G. **Disclosure of Confidential Material:** If a party or attorney wishes to disclose any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or the contents thereof, to any person actively working, or retained to work on this action (e.g., expert witness or consultant), the person making the disclosure shall, in addition to the duties under Paragraph II.F, do the following:

- (1) Instruct the person to whom disclosure is made to return or, in the alternative and with permission of the producing party, at the conclusion of the case to destroy any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, including notes or memoranda made from **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material;
- (2) Maintain a list of persons to whom disclosure was made and the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials which were disclosed to that person; and
- (3) At the conclusion of this action, gather the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials, copies thereof, and related notes

1 and memoranda, and return them to the party or attorney who originally
 2 disclosed them, or destroy them, providing a certificate of compliance
 3 with the terms of this Protective Order. If counsel for one party have
 4 created work product incorporating, describing or referring to another
 5 party's **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** documents,
 6 counsel who have created the work product must collect all copies from
 7 experts and other consultants and must return or destroy all copies of
 8 **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** documents attached
 9 to the work product. However, the counsel that created the work product
 10 may retain the work product itself once all copies are collected and all
 11 copies of **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** documents
 12 are returned or destroyed. No work product incorporating, describing or
 13 referring to another party's **CONFIDENTIAL** or **HIGHLY**
 14 **CONFIDENTIAL** documents may be disseminated to any person or used
 15 for any purpose once the action is concluded.

16 H. **Use of Confidential Material Limited To This Action:** No person or party
 17 subject to this Order shall distribute, transmit, or otherwise divulge any material
 18 marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, except in
 19 accordance with this Order. Furthermore, any document or other material which
 20 is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or the contents
 21 thereof, may be used by a party, or a party's counsel, expert witness, consultant,
 22 or other person to whom disclosure is made, only for the purpose of this action.

23 I. **Designation of Material Disclosed or Produced at Depositions:** All transcripts
 24 and exhibits shall be treated as if designated **CONFIDENTIAL** for a period of 30
 days after the transcript is received from the court reporter. Counsel for any party
 may designate during the deposition or during the thirty-day period after the
 transcript is received from the court reporter any portion of the transcript as
CONFIDENTIAL or **HIGHLY CONFIDENTIAL** by denominating by page

and line, and by designating any exhibits, that are to be considered

CONFIDENTIAL or **HIGHLY CONFIDENTIAL** pursuant to the criteria set forth in this Order. Such designation shall be communicated to all parties.

Transcript portions and exhibits designated in accordance with this paragraph shall be disclosed only in accordance with this Order. A party may challenge the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** designation or portions thereof in accordance with the provisions of Paragraph II.M below.

J. **Use of HIGHLY CONFIDENTIAL Material at Depositions:** If a party intends to use material that has been marked as **HIGHLY CONFIDENTIAL** during the deposition of an individual or entity other than the designating party, then the party shall notify the designating party 10 days in advance of the deposition that it intends to use that material. The parties shall then attempt to agree on the parameters for usage of the material at the deposition, including (a) the creation of a mutually acceptable redacted version that suffices for purposes of the deposition; and (b) whether other non-**HIGHLY CONFIDENTIAL** material may be used for the same purposes. If the parties cannot agree on the usage of such material at deposition, then either party may seek the Court's direction.

K. **Disclosure Requirements for HIGHLY CONFIDENTIAL Information to Competitor Related Consultants:** Prior to disclosure, Plaintiff will inform the producing party of the intent to disclose **HIGHLY CONFIDENTIAL** material to anyone who is currently, or who at any time during the pendency of this litigation becomes, an employee or consultant to a competitor (as such individuals are defined in Paragraph II.C above) in the manner set forth below:

- (1) Give at least 21 days notice in writing to counsel for the party who designated such information as **HIGHLY CONFIDENTIAL** of the intent to so disclose that information, although the disclosing party is not required to identify the intended recipient of such materials.

- 1 (2) Within 10 days thereafter, counsel for the parties shall attempt to resolve
2 any disputes between them regarding the production of the **HIGHLY**
3 **CONFIDENTIAL** material to the intended individuals.
- 4 (3) If the parties are unable to resolve any dispute regarding such production,
5 within an additional 7 days, the party who designated the information in
6 question as **HIGHLY CONFIDENTIAL** shall file a motion objecting to
7 the proposed disclosure. In making such motion, it shall be the producing
8 party's burden to demonstrate good cause for preventing the disclosure.
- 9 (4) If the Court permits disclosure of the material designated as **HIGHLY**
10 **CONFIDENTIAL** at issue, the information remains designated as
11 **HIGHLY CONFIDENTIAL** and the individual receiving such
information shall be bound by the requirements of this Order.

12 L. **Third-Party Subpoenas and Document Requests:** If any person or entity
13 possessing **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials is
14 subpoenaed in another action or proceeding or served with a document demand,
15 and such subpoena or document requests the production of **CONFIDENTIAL** or
16 **HIGHLY CONFIDENTIAL** materials, the person receiving the subpoena or
17 document demand shall, within 5 days, give written notice to counsel for the
18 producing party, and shall, to the extent permitted by law, court rule, and court
19 order, (1) withhold production of the requested **CONFIDENTIAL** or **HIGHLY**
20 **CONFIDENTIAL** materials until the producing party permits production, or
until a court of competent jurisdiction orders otherwise, and (2) seek to enable the
21 producing part to move to quash or limit the subpoena or document demand.

22 M. **Challenges to Designations or Redacted Information:** Any party may at any
23 time challenge the designation of material as **CONFIDENTIAL** or **HIGHLY**
24 **CONFIDENTIAL** or the redaction of information by providing written notice of
its objection to the designating party, or, in the case of a deposition, either on the
record at a deposition or in writing later. If, after a meet-and-confer process, the

1 parties cannot reach agreement, either the designating party or challenging party
 2 may, on reasonable notice, apply for an appropriate ruling from the Court. The
 3 disputed material, including all references to the substance of such material shall
 4 be filed under seal as provided in Paragraph III.A. The disputed material shall
 5 continue to be treated as designated, or redacted, until the Court orders otherwise.
 6 In any such application concerning a ruling on confidentiality or redacted
 7 information, the party claiming the designation of confidentiality or redaction has
 8 the burden of establishing that such confidential designation or redaction is
 proper.

9 N. **Inadvertent Failure to Properly Designate Confidential Material:** Inadvertent
 10 production of any document or information without a designation of
 11 **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** will not be deemed to waive
 12 a party's claim to its confidential nature or prevent said party from designating
 13 said document or information as **CONFIDENTIAL** or **HIGHLY**
 14 **CONFIDENTIAL** at a later date. Disclosure of said document or information by
 15 the receiving party prior to such later designation shall not be deemed a violation
 16 of the provisions of this Order, but the receiving party shall make good faith and
 17 reasonable efforts to retrieve any **CONFIDENTIAL** or **HIGHLY**
 18 **CONFIDENTIAL** material that has been previously disclosed to persons not
 entitled to receive them.

19 O. **Inadvertent Disclosure of Privileged Documents, "Clawback" Procedure:**
 20 Inadvertent production of documents or information (collectively "Inadvertently
 21 Produced Documents") subject to the attorney-client privilege, work product
 22 doctrine and/or any other applicable privilege protecting information from
 23 discovery shall not constitute a waiver of the privilege and shall be governed by
 24 Federal Rule of Civil Procedure 26(b)(5) and Federal Rule of Evidence 502 and
 the clawback and waiver provisions contained therein.

1 **III. USE AND SUBMISSION OF CONFIDENTIAL MATERIAL**

2 **A. Use In Court Filings:** Where a party intends to include material designated as
3 **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or information derived from
4 **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material in any court filing,
5 the party shall notify the designating party and provide copies of the material or
6 excerpts containing the material that it intends to file at least 7 days prior to
7 making the filing. The filing party shall file the **CONFIDENTIAL** or **HIGHLY**
8 **CONFIDENTIAL** material in accordance with LR 10-5. The designating party
9 will then be responsible for filing a motion for leave to seal the documents to be
10 filed concurrently or shortly after the filing of the Motion. All filings and motions
11 to seal shall be made with reference to the requirements of *Kamakana v. City and*
12 *County of Honolulu*, 447 F.3d 1172, 1180 (9th Cir. 2006) and shall make the
13 showing of either “good cause” or “compelling reasons” sufficient to overcome
14 the presumption of public access as outlined in that case. Absent written
15 permission or a Court order, material designated as **CONFIDENTIAL** or
16 **HIGHLY CONFIDENTIAL** or information derived from such may not be filed
17 in the public record.

18 **B. Use In Hearings or Trial:** If any party or attorney wishes to file, or use as an
19 exhibit or as testimonial evidence at a hearing or trial, any **CONFIDENTIAL** or
20 **HIGHLY CONFIDENTIAL** material, such party must provide 10 days notice to
21 the producing party of the intended use of such information. The parties shall then
22 attempt to resolve the matter of continued confidentiality by either (a) removing
23 the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** marking, (b) creating a
24 mutually acceptable redacted version that suffices for purposes of the action, or
(c) conferring about methods to avoid or limit public disclosure of such
information during testimony. If an amicable resolution proves unsuccessful, the
parties may present the issue to the Court for resolution. The proponent of

1 continued confidentiality will have the burden of persuasion that the document or
2 material should be withheld from the public record.

3 C. **Survival of Protective Order:** Throughout and after the conclusion of this
4 litigation, including any appeals, the restrictions on communication and disclosure
5 provided for herein shall continue to be binding upon the parties and all other
6 persons to whom **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material
7 has been communicated or disclosed pursuant to the provisions of this Order or
8 any other order of the Court. The Court shall retain jurisdiction to enforce the
9 terms of this Order.

10 D. **Return or Destruction of CONFIDENTIAL Material Upon Termination of**
11 **Litigation:** Within 60 days after the final termination of this action, including any
12 appeals, each party, upon request of the other party, shall either return to the
13 producing party, or destroy, all **CONFIDENTIAL** and **HIGHLY**
14 **CONFIDENTIAL** material designated by any other party (including any such
15 material disclosed to third persons), except for any attorneys' work-product for
16 the party returning the material, and shall provide confirmation in writing to
17 opposing counsel if such materials are destroyed.

18 E. **Modification of this Order:** Nothing in this Order shall prevent any other party
19 from seeking amendments broadening or restricting the rights of access to or the
20 use of **CONFIDENTIAL** and/or **HIGHLY CONFIDENTIAL** material or
21 otherwise modifying this Order; and this Order may be amended without leave of
22
23
24

the Court by the agreement of the undersigned attorneys for the parties in the form
of a Stipulation that shall be filed in this case.

BOWEN LAW OFFICES

KAEMPFER CROWELL

By: /s/ Jerome R. Bowen

By: /s/ Robert McCoy

Jerome R. Bowen, No. 4540
Sarah M. Banda, No. 11909
9960 West Cheyenne Avenue
Suite 250
Las Vegas, Nevada 89129

Robert McCoy, No. 9121
1980 Festival Plaza Drive
Suite 650
Las Vegas, Nevada 89135

Attorneys for Plaintiff Sharon Hardman

Attorneys for Defendants St. Jude
Medical, S.C., Inc. and Advanced
Neuromodulation Systems, Inc.

ORDER

IT IS SO ORDERED.



UNITED STATES MAGISTRATE JUDGE

DATED: February 9, 2016

KAEMPFER CROWELL
Robert McCoy, No. 9121
1980 Festival Plaza Drive
Suite 650
Las Vegas, Nevada 89135
Telephone: (702) 792-7000
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**EXHIBIT A: AGREEMENT TO BE
BOUND BY STIPULATED
CONFIDENTIALITY AGREEMENT
AND PROTECTIVE ORDER**

I have read and understand the Stipulated Confidentiality Agreement and Protective Order entered in the above-captioned action, and I agree to be bound by its terms. Specifically, and without limitation upon such terms, I agree not to use or disclose any confidential material and information made available to me other than in accordance with the Protective Order.

I hereby agree to submit to the jurisdiction of this Court for enforcement of the undertaking I have made herein.

Dated: _____

Signed name: _____

Printed name: _____